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IN THE
Supreme Court of the United States
OCTOBER TERM, 1994

BRISTOL-MYERS SQUIBB COMPANY,
Petitioner,
v.
ZENITH LABORATORIES, INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF IN OPPOSITION BY RESPONDENT ZENITH LABORATORIES, INC.

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QUESTIONS PRESENTED

1. Whether the court of appeals properly held that literal infringement required a comparison of the accused product to the claim of the patent rather than a commercial embodiment.

2. Whether the court of appeals properly applied the doctrine of equivalents in light of the prosecution history.

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INTRODUCTION

The petition purports to present for review two questions of patent law. *See* Petition (i). Neither of the questions is raised by the decision below. In addition, the presentation of the first issue is based on both a misstatement of fact and on the assertion of scientific opinion which is not in the record.

REASONS FOR DENYING THE WRIT

I. PETITIONER FAILED TO PROVE LITERAL INFRINGEMENT

The United States Court of Appeals for the Federal Circuit ruled that Bristol-Myers Squibb Company ("Bristol") failed to prove literal infringement. The ruling was

based on the well-established principle that an accused product must be compared to the claim of the patent, not a commercial embodiment. Petition 11a. Bristol had compared the accused product only to a reference x-ray diffraction pattern derived from its commercial product. In response to Bristol's assertion on appeal that comparison of the reference pattern to the patent pattern showed them to be the same, the court of appeals concluded that the reference pattern, which had only 22 of the 37 x-ray diffraction lines recited in the patent, did not match the claim. The court of appeals based this conclusion on a construction of the language of the claim itself. *Id.* 11a-12a.

The petition describes a ruling never made by the court of appeals, It states,

> The court of appeals in this case held that it was error for a court, addressing a charge of infringement, "to compare . . . the accused product or process with the patentee's commercial embodiment or other version of the product or process," *even if,* as a scientific matter, the commercial product is exactly the same as the patented article. Pet. App. 11a. (emphasis in original).

Petition 11.

As the placement of the quotation marks indicates, the court of appeals never said anything about the commercial product being exactly the same as the patented product, as a scientific matter. The record, in fact, presented no occasion for addressing the correct legal treatment of a scientifically exact reference. Bristol never attempted to prove in any way that the reference pattern and the product pattern were scientifically identical.

Contrary to petitioner's statement, it is not the case that Dr. Brittain "took x-ray diffraction readings of DURICEF and matched them (21 of 22 lines, or angles) with the diffraction figures set out in the patent." Petition 8. Dr. Brittain never made any such comparison. It was the

district court that made the comparison, on its own, after the trial. The paragraph of the decision cited by petitioner makes that clear. Petition 50a.

Petitioner also denounces "the inevitable waste and difficulties in having to prove infringement through efforts to match every bit of scientifically redundant data in a patent claim. . . ." Petition 17-18. But there is no evidence that any data in the claim is redundant. Dr. Brittain offered no testimony that he chose to use a reference pattern because using the patent pattern would have been too onerous. In fact, he offered no testimony at all on why he chose to use a reference pattern. Statements of purported scientific opinion appearing in the petition are simply not in the record. *See, e.g.,* Petition 8 n.7, 18 n.14.

Petitioner raises asserted problems for new claimants—and, indeed, the public—as inventors are forced to wrestle with the problem of over or under inclusion of "information in their claims . . . ." Petition 18-19. Petitioner determined how to write the Bouzard claim. Neither the district court nor the court of appeals had any input in that decision. It was petitioner that chose to claim a thirty-seven line diffraction pattern. In presenting its claim, petitioner stated:

> New cefadroxil monohydrate has a highly crystalline character allowing for the measurement of 37 X-ray diffraction lines different and distinct in pattern from that of cefadroxil trihydrate which had also a highly crystalline character permitting the measurement of 38 X-ray diffraction lines (Weber, paragraph 7 and Exhibit VI). Old cefadroxil monohydrate was a poorly crystalline material allowing measurement of only 18 X-ray diffraction lines (Weber, paragraph 5). A 4333-34

At bottom, the first issue presented by the petition comes down to a jeremiad of petitioner's own choices. They are fact-intensive to this case alone. They present no issue of general importance.

II. THE EQUIVALENTS RULING IS BASED ON THE PROSECUTION HISTORY

Similarly, the second issue presented by the petition is foreclosed from any general importance by the particular facts of this case, and specifically by petitioner's own actions during prosecution of the patent application. In the words of the court of appeals:

> In view of Bristol's numerous statements in the prosecution history regarding the superior manufacturing-related benefits of the Bouzard crystal in relation to the prior forms of cefadroxil, it is clear that the primary, if not the only, function of the Bouzard crystal form of the drug as compared to other forms is to facilitate pre-ingestion manufacturing. No other intended function is described or suggested.

Petition 15a (footnote omitted).

This is not the pronouncement of a broad new principle of law. It is a finding of fact grounded firmly in the record of this case.

What is more, the second issue is really no more than a play on words. Petitioner remonstrates that the court of appeals improperly limited the function step of the function/way/result test to a new function. That new function, of course, was the manufacturing advantages of the Bouzard monohydrate.

Petitioner would have it that the function of the patented crystal is delivery of therapeutic value. But if that were so, surely the way Bouzard delivers therapeutic value is by facilitating the manufacture of DURICEF. If the way were by absorption into the bloodstream, as petitioner suggests, the existence of the Bouzard crystal structure would be irrelevant. The result is that the manufacturing advantages must be described either as function or as way, and either description produces the conclusion that cefadroxil DC does not infringe the Bouzard patent.

Beyond that, petitioner specifically eschewed therapeutic value in its pursuit of the Bouzard patent. On April 9,

1979, Edel Berman, petitioner's Director of Medical Research, submitted an affidavit, which in paragraph 6 provided support for "the conclusion that new cefadroxil monohydrate affords a higher, more prolonged concentration of cefadroxil antibiotic activity in the blood than either old cefadroxil monohydrate or cefadroxil trihydrate." A 4450. On December 17, 1984, Dr. Berman submitted a new affidavit in which he "reconsidered the conclusions which I had drawn" and withdrew the conclusion in paragraph 6. A 4798. All that remained was manufacturing advantages.

The court of appeals simply took the facts as it found them in the prosecution history. Those facts establish that the Bouzard patent's function was manufacturing advantages.

CONCLUSION

For the reasons stated above, the petition should be denied.

Respectfully submitted,

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